

1632/IFW

DOCKET NO.: C1040.70010US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: McCluskie et al.  
Serial No.: 09/768,012  
Confirmation No.: 9273  
Filed: January 22, 2001  
For: IMMUNOSTIMULATORY NUCLEIC ACIDS FOR  
INDUCING A TH2 IMMUNE RESPONSE  
Examiner: Dave Trong Nguyen  
Art Unit: 1632

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 25 day of October, 2004.

  
Kristin J. Ketelhut

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| <u>Docket No.</u>            | <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> |
|------------------------------|-------------------|--------------------|--------------------|
| C1037.70013US01              | 10/831,778        | April 23, 2004     | Bratzler et al.    |
| C1037.70039US01              | 10/816,220        | April 1, 2004      | McCluskie et al.   |
| C1037.70048US00              | 10/644,052        | August 19, 2003    | Jurk et al.        |
| C1037.70049US00              | 10/643,141        | August 18, 2003    | Hutcherson et al.  |
| C1037.70052US00              | 10/668,050        | September 22, 2003 | Bratzler et al.    |
| <sup>1</sup> C1039.70020US01 | 10/921,086        | August 18, 2004    | Krieg et al.       |
| <sup>2</sup> C1039.70035US01 | 10/884,866        | July 2, 2004       | Krieg et al.       |
| <sup>2</sup> C1039.70035US02 | 10/888,803        | July 9, 2004       | Krieg et al.       |
| C1039.70048US02              | 10/817,165        | April 2, 2004      | Krieg et al.       |
| <sup>3</sup> C1039.70048US03 | 10/831,647        | April 23, 2004     | Krieg et al.       |
| <sup>3</sup> C1039.70048US04 | 10/847,642        | May 15, 2004       | Krieg et al.       |
| <sup>3</sup> C1039.70048US05 | 10/877,407        | June 24, 2004      | Krieg et al.       |
| <sup>3</sup> C1039.70048US06 | 10/884,852        | July 2, 2004       | Krieg et al.       |
| <sup>3</sup> C1039.70048US07 | 10/888,785        | July 9, 2004       | Krieg et al.       |
| <sup>3</sup> C1039.70048US08 | 10/888,449        | July 9, 2004       | Krieg et al.       |
| <sup>3</sup> C1039.70048US09 | 10/894,657        | July 16, 2004      | Krieg et al.       |
| <sup>3</sup> C1039.70048US10 | 10/894,862        | July 16, 2004      | Krieg et al.       |
| <sup>3</sup> C1039.70048US11 | 10/928,762        | August 26, 2004    | Krieg et al.       |
| <sup>4</sup> C1039.70057US01 | 10/838,659        | May 3, 2004        | Davis et al.       |

<sup>1</sup>Copy not enclosed; see C1039.70020US00, Serial No. 09/337,584 for identical specification

<sup>2</sup>Copy not enclosed; see C1039.70035US00, Serial No. 09/699,187 for identical specification

<sup>3</sup>Copy not enclosed; see C1039.70048US02, Serial No. 10/817,165 for identical specification

<sup>4</sup>Copy not enclosed; see C1039.70057US00, Serial No. 09/965,101 for identical specification

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Art Unit: 1632

| <u>Docket No.</u>            | <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> |
|------------------------------|-------------------|--------------------|--------------------|
| C1039.70058US01              | 10/831,775        | April 23, 2004     | Davis et al.       |
| C1039.70083US03              | 10/788,199        | February 26, 2004  | Krieg et al.       |
| <sup>5</sup> C1039.70083US08 | 10/847,650        | May 15, 2004       | Krieg et al.       |
| <sup>5</sup> C1039.70083US09 | 10/888,885        | July 9, 2004       | Krieg et al.       |
| <sup>5</sup> C1039.70083US10 | 10/888,089        | July 9, 2004       | Krieg et al.       |
| C1039.70084US00              | 10/649,584        | August 25, 2003    | Krieg et al.       |
| <sup>6</sup> C1040.70006US01 | 10/888,886        | July 9, 2004       | McCluskie et al.   |
| C1040.70012US00              | 10/644,267        | August 20, 2003    | Davis et al.       |
| <sup>7</sup> C1041.70002US01 | 10/877,369        | June 25, 2004      | Wagner et al.      |
| <sup>7</sup> C1041.70002US02 | 10/876,965        | June 25, 2004      | Wagner et al.      |
| <sup>7</sup> C1041.70002US03 | 10/876,892        | June 25, 2004      | Wagner et al.      |
| <sup>8</sup> C1041.70005US01 | 10/811,226        | March 26, 2004     | Wagner et al.      |
| <sup>8</sup> C1041.70005US02 | 10/894,655        | July 16, 2004      | Wagner et al.      |
| C1041.70016US01              | 10/884,372        | July 2, 2004       | Bauer et al.       |
| C1041.70024WO00              | PCT/US04/12788    | April 22, 2004     | Vollmer et al.     |
| C1041.70036US01              | 10/872,196        | June 18, 2004      | Lipford et al.     |
| C1041.70040US00              | 10/666,844        | September 19, 2003 | Lipford et al.     |

<sup>5</sup>Copy not enclosed; see C1039.70083US03, Serial No. 10/788,199 for identical specification

<sup>6</sup>Copy not enclosed; see C1040.70006US00, Serial No. 09/316,199 for identical specification

<sup>7</sup>Copy not enclosed; see C1041.70002US00, Serial No. 09/241,653 for identical specification

<sup>8</sup>Copy not enclosed; see C1041.70005US00, Serial No. 09/355,254 for identical specification

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

| <u>Docket No.</u> | <u>Serial No.</u> | <u>Mailing Date</u> | <u>Type of Communication</u>                 |
|-------------------|-------------------|---------------------|--|
| C1040.70010WO00   | PCT/US01/02170    | 7 June 2001         | International Search Report                  |
| C1040.70010WO00   | PCT/US01/02170    | 13 September 2001   | Written Opinion                              |
| C1040.70010WO00   | PCT/US01/02170    | 18 January 2002     | International Preliminary Examination Report |

The following are remarks concerning the other information cited:

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

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Conf. No.: 9273

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Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*McCluskie et al., Applicant*

By:



Maria A. Trevisan, Reg. No. 48,207  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1040.70010US00  
Date: October 25, 2004  
**xNDDx**



DOCKET NO.: C1040.70010US00

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IMMUNUE RESPONSE  
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Kristin J. Ketelhut

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MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*McCluskie et al., Applicant*

By:

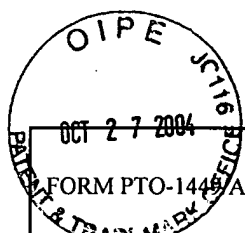


Maria A. Trevisan, Reg. No.: 48,207  
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Telephone: (617) 646-8000

Docket No.: C1040.70010US00

Date: October 25 2004

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|   |   |    |    |                               |                                   |
|---|---|----|----|-------------------------------|-----------------------------------|
| <b>FORM PTO-1449 A and B (Modified)</b><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   |    |    | APPLICATION NO.: 09/768,012   | ATTY. DOCKET NO.: C1040.70010US00 |
|   |   |    |    | FILING DATE: January 22, 2001 | CONFIRMATION NO.: 9273            |
|   |   |    |    | APPLICANT: McCluskie et al.   |                                   |
|   |   |    |    | GROUP ART UNIT: 1632          | EXAMINER: Dave Trong Nguyen       |
| Sheet   | 1 | of | 13 |                               |                                   |

**U.S. PATENT DOCUMENTS**

| Examiner's<br>Initials | Cite<br>No. | U.S. Patent Document |              | Name of Patentee or Applicant of Cited<br>Document | Date of Publication or of issue<br>of Cited Document<br>MM-DD-YYYY |
|------------------------|-------------|----------------------|--------------|--|--|
|                        |             | Number               | Kind<br>Code |  |  |
|                        | A44         | 6,653,292            | B1           | Krieg et al.                                       | 11-25-2003   |
|                        | A45         | 6,727,230            | B1           | Hutcherson et al.                                  | 04-27-2004   |
|                        | A46         | 2002-0064515         | A1           | Krieg et al.                                       | 05-30-2002   |
|                        | A47         | 2002-0091097         | A1           | Bratzler et al.                                    | 07-11-2002   |
|                        | A48         | 2002-0156033         | A1           | Bratzler et al.                                    | 10-24-2002   |
|                        | A49         | 2002-0164341         | A1           | Davis et al.                                       | 11-07-2002   |
|                        | A50         | 2002-0165178         | A1           | Schetter et al.                                    | 11-07-2002   |
|                        | A51         | 2002-0198165         | A1           | Bratzler et al.                                    | 12-26-2002   |
|                        | A52         | 2003-0026782         | A1           | Krieg et al.                                       | 02-06-2003   |
|                        | A53         | 2003-0026801         | A1           | Weiner et al.                                      | 02-06-2003   |
|                        | A54         | 2003-0050261         | A1           | Krieg et al.                                       | 03-13-2003   |
|                        | A55         | 2003-0050263         | A1           | Krieg et al.                                       | 03-13-2003   |
|                        | A56         | 2003-0050268         | A1           | Krieg et al.                                       | 03-13-2003   |
|                        | A57         | 2003-0055014         | A1           | Bratzler   | 03-20-2003   |
|                        | A58         | 2003-0087848         | A1           | Bratzler et al.                                    | 05-08-2003   |
|                        | A59         | 2003-0091599         | A1           | Davis et al.                                       | 05-15-2003   |
|                        | A60         | 2003-0100527         | A1           | Krieg et al.                                       | 05-29-2003   |
|                        | A61         | 2003-0104523         | A1           | Bauer et al.                                       | 06-05-2003   |
|                        | A62         | 2003-0139364         | A1           | Krieg et al.                                       | 07-24-2003   |
|                        | A63         | 2003-0148316         | A1           | Lipford et al.                                     | 08-07-2003   |
|                        | A64         | 2003-0148976         | A1           | Krieg et al.                                       | 08-07-2003   |
|                        | A65         | 2003-0166001         | A1           | Lipford  | 09-04-2003   |
|                        | A66         | 2003-0181406         | A1           | Schetter et al.                                    | 09-25-2003   |
|                        | A67         | 2003-0191079         | A1           | Krieg et al.                                       | 10-09-2003   |
|                        | A68         | 2003-0212026         | A1           | Krieg et al.                                       | 11-13-2003   |
|                        | A69         | 2003-0224010         | A1           | Davis et al.                                       | 12-04-2003   |
|                        | A70         | 2003-0232074         | A1           | Lipford et al.                                     | 12-18-2003   |
|                        | A71         | 2004-0009949         | A1           | Krieg  | 01-15-2004   |
|                        | A72         | 2004-0030118         | A1           | Wagner et al.                                      | 02-12-2004   |
|                        | A73         | 2004-0053880         | A1           | Krieg  | 03-18-2004   |
|                        | A74         | 2004-0067905         | A1           | Krieg  | 04-08-2004   |
|                        | A75         | 2004-0087534         | A1           | Krieg et al.                                       | 05-06-2004   |
|                        | A76         | 2004-0087538         | A1           | Krieg et al.                                       | 05-06-2004   |
|                        | A77         | 2004-0092472         | A1           | Krieg  | 05-13-2004   |
|                        | A78         | 2004-0106568         | A1           | Krieg et al.                                       | 06-03-2004   |
|                        | A79         | 2004-0131628         | A1           | Bratzler et al.                                    | 07-08-2004   |
|                        | A80         | 2004-0132685         | A1           | Krieg et al.                                       | 07-08-2004   |

|   |   |    |    |                               |  |                                   |  |
|---|---|----|----|-------------------------------|--|-----------------------------------|--|
| <b>FORM PTO-1449/A and B (Modified)</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   |    |    | APPLICATION NO.: 09/768,012   |  | ATTY. DOCKET NO.: C1040.70010US00 |  |
|   |   |    |    | FILING DATE: January 22, 2001 |  | CONFIRMATION NO.: 9273            |  |
|   |   |    |    | APPLICANT: McCluskie et al.   |  |                                   |  |
|   |   |    |    | GROUP ART UNIT: 1632          |  | EXAMINER: Dave Trong Nguyen       |  |
| Sheet   | 2 | of | 13 |                               |  |                                   |  |

|  |      |              |    |                 |            |
|--|------|--------------|----|-----------------|------------|
|  | A81  | 2004-0142469 | A1 | Krieg et al.    | 07-22-2004 |
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|  | A89  | 2004-0167089 | A1 | Krieg et al.    | 08-26-2004 |
|  | A90  | 2004-0171150 | A1 | Krieg et al.    | 09-02-2004 |
|  | A91  | 2004-0171571 | A1 | Krieg et al.    | 09-02-2004 |
|  | A92  | 3,906,092    |    | Hilleman et al. | 09-16-1975 |
|  | A93  | 4,452,775    |    | Kent            | 06-05-1984 |
|  | A94  | 4,544,559    |    | Gil et al.      | 10-01-1985 |
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|  | A97  | 5,066,500    |    | Gil et al.      | 11-19-1991 |
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|  | A102 | 5,457,189    |    | Crooke et al.   | 10-10-1995 |
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|  | A107 | 5,705,385    |    | Bally et al.    | 01-06-1998 |
|  | A108 | 5,753,613    |    | Ansell et al.   | 05-19-1998 |
|  | A109 | 5,756,097    |    | Landucci et al. | 05-26-1998 |
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|  | A112 | 5,814,335    |    | Webb et al.     | 09-29-1998 |
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|  | A114 | 5,932,556    |    | Tam             | 08-03-1999 |
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|  | A116 | 5,976,567    |    | Wheeler et al.  | 11-02-1999 |
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|   |   |    |    |                               |  |                                   |  |
|---|---|----|----|-------------------------------|--|-----------------------------------|--|
| <b>FORM PTO-1449/A and B (Modified)</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   |    |    | APPLICATION NO.: 09/768,012   |  | ATTY. DOCKET NO.: C1040.70010US00 |  |
|   |   |    |    | FILING DATE: January 22, 2001 |  | CONFIRMATION NO.: 9273            |  |
|   |   |    |    | APPLICANT: McCluskie et al.   |  |                                   |  |
|   |   |    |    | GROUP ART UNIT: 1632          |  | EXAMINER: Dave Trong Nguyen       |  |
| Sheet   | 3 | of | 13 |                               |  |                                   |  |

|  |      |              |    |                      |            |
|--|------|--------------|----|----------------------|------------|
|  | A121 | 6,042,838    |    | Briles et al.        | 03-28-2000 |
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|  | A123 | 6,110,745    |    | Zhang et al.         | 08-29-2000 |
|  | A124 | 6,184,369    | B1 | Rando et al.         | 02-06-2001 |
|  | A125 | 6,191,257    | B1 | Ledley et al.        | 02-20-2001 |
|  | A126 | 6,225,292    | B1 | Raz et al.           | 05-01-2001 |
|  | A127 | 6,248,720    | B1 | Mathiowitz et al.    | 06-19-2001 |
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|  | A129 | 6,498,148    | B1 | Raz                  | 12-24-2002 |
|  | A130 | 6,503,533    | B1 | Korba et al.         | 01-07-2003 |
|  | A131 | 6,514,948    | B1 | Raz et al.           | 02-04-2003 |
|  | A132 | 6,534,062    | B1 | Raz et al.           | 03-18-2003 |
|  | A133 | 6,544,518    | B1 | Friede et al.        | 04-08-2003 |
|  | A134 | 6,552,006    | B2 | Raz et al.           | 04-22-2003 |
|  | A135 | 6,562,798    | B1 | Schwartz             | 05-13-2003 |
|  | A136 | 6,589,940    | B1 | Raz et al.           | 07-08-2003 |
|  | A137 | 6,610,661    | B1 | Carson et al.        | 08-26-2003 |
|  | A138 | 6,613,751    | B1 | Raz et al.           | 09-02-2003 |
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|  | A142 | 2001-0041681 | A1 | Phillips et al.      | 11-15-2001 |
|  | A143 | 2001-0046967 | A1 | Van Nest et al.      | 11-29-2001 |
|  | A144 | 2002-0028784 | A1 | Van Nest et al.      | 03-07-2002 |
|  | A145 | 2002-0055477 | A1 | Van Nest et al.      | 05-09-2002 |
|  | A146 | 2002-0086839 | A1 | Raz et al.           | 07-04-2002 |
|  | A147 | 2002-0098199 | A1 | Van Nest et al.      | 07-25-2002 |
|  | A148 | 2002-0107212 | A1 | Van Nest et al.      | 08-08-2002 |
|  | A149 | 2002-0142978 | A1 | Raz et al.           | 10-03-2002 |
|  | A150 | 2003-0022852 | A1 | Van Nest et al.      | 01-30-2003 |
|  | A151 | 2003-0059773 | A1 | Van Nest et al.      | 03-27-2003 |
|  | A152 | 2003-0072762 | A1 | Van de Winkel et al. | 04-17-2003 |
|  | A153 | 2002-0078223 | A1 | Baldonado et al.     | 06-20-2002 |
|  | A154 | 2003-0104044 | A1 | Semple et al.        | 06-05-2003 |
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|  | A156 | 2003-0119774 | A1 | Foldvari et al.      | 06-26-2003 |
|  | A157 | 2003-0125279 | A1 | Junghans et al.      | 07-03-2003 |
|  | A158 | 2003-0125284 | A1 | Raz et al.           | 07-03-2003 |
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|  | A160 | 2003-0129251 | A1 | Itakura et al.       | 09-12-2002 |

|   |   |    |    |                               |  |                                   |  |
|---|---|----|----|-------------------------------|--|-----------------------------------|--|
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| FORM PTO-1449/A and B (Modified)<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |    |    |    | APPLICATION NO.: 09/768,012   |  | ATTY. DOCKET NO.: C1040.70010US00 |  |
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| Sheet  | 13 | of | 13 |                               |  |                                   |  |

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| EXAMINE R | DATE CONSIDERED |
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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